July 21, 2022

Sakshi Narkhede, MS- RA
Regulatory Affairs Associate
Adaptive Biotechnologies Corporation
1551 Eastlake Avenue East, Suite 200,
Seattle, WA 98102 USA

Re: EUA203162/S003
Trade/Device Name: T-Detect COVID Test
Dated: April 29, 2022
Received: April 29, 2022

Dear Sakshi Narkhede:

This is to notify you that your request to update the T-Detect COVID Test submission with data and information to fulfill Condition of Authorization K. from the September 2, 2021 Letter of Authorization, demonstrating that the current T-Detect algorithm software is robust in its performance with respect to new variant strains, is granted. Upon review, we concur that the data and information submitted in EUA203162/S003 fulfills Condition of Authorization K. from the September 2, 2021 letter. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the T-Detect COVID Test re-issued on September 2, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health